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Specification and Drawing, as originally filed, with Application for Patent Serial No: **2,281,335**, on September 2, 1999, by **DR. KIERAN J. MURPHY**, for "Method and Apparatus for Strengthening and Augmenting Vertebral Bodies".

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Percutaneous vertebroplasty was invented in 1984 in France Dr. Herve Deramond. This procedure involves the injection of bone cement into a vertebral body via a percutaneous route under X-ray guidance. The cement is injected as a semi liquid substance via a needle an 11-14 gauge in size that has been passed into the vertebral body via a transpedicular or posterolateral or less often a posterolateral approach. The three main indications are benign osteoporotic fractures, malignant metastatic disease and benign tumors of the bone (1-16). Vertebroplasty is performed in all these indications to achieve pain relief.

The aim of percutaneous vertebroplasty is to get a structural reinforcement of the vertebral body through the injection by a minimally invasive percutaneous approach of bone cement into the vertebral body (1). This results in increased structural integrity, decreased micromotion at the fracture site, and possibly a destruction of pain fibers due to the heat of the bone cement as it polymerizes and sets. In the appropriate candidate we can achieve complete pain relief in up to 90 % of patients. The cement should have properties of increasing vertebral body stiffness and compressive strength. It should be liquid enough to flow into fracture planes and to fuse them. The thermal properties of cement are debated but a heating effect may be beneficial and may cause death to local nerve endings involved in pain stimulation. Most of the pain relief is related to the increased structural integrity.

There is an increasing public awareness of the procedure. This is the only procedure that I perform in which patients approach me directly. Patients become aware of it in chat rooms on the web about osteoporosis and fractures. At the moment, more than4000 patients have been treated worldwide. If we consider only patients with osteoporotic

induced compression fractures, there are 500,000 to 700,000 per year in the US. Of this population it is thought that 150,000 patients per year eligible for the procedure because of unrelenting pain refractory to conventional therapy. Conventional therapy consists of bed rest bracing, and anti-inflammatory or commonly opiate medications. This is associated with pneumonia, deep venous thrombosis from bed rest and pulmonary embolism. There is therefore no adequate alternative to vertebroplasty for these patients. The European experience includes many patients with cancer and destructive metastatic deposits in the vertebrae, which we will see from the references below, respond well to this technique. Clinical results have been reported in more than 30 academic peer review publications in Radiology, American Journal of Neuroradiology, Radiologic Clinics of North America, and other journals.

How is the procedure done?

In a radiology department the patient is placed in the prone position and under X ray Guidance the skin overlying the fractured vertebrae is prepped and draped. 1% Lidocaine is injected into the skin underlying fat and into the periosteum of the pedicle to be entered. A 5-mm skin incision is made with a no.11 scalpel blade. The decision regarding which pedicle to use is made based on CT and MR images. An 11gauge needle, (13 gauge in a smaller vertebral body) is passed down the pedicle until it enters the vertebral body and reaches the junction of the anterior and middle thirds. This area is the region of maximum mechanical moment and usually the area of greatest compression. At this point some practitioners perform a vertebrogram, (the injection of non ionic X ray contrast into the vertebral body to look for large veins). Many physicians however don't do this.

Cement mixing.

Barium powder is mixed with methyl methacrylate powder and then monomer liquid is added to the mixture. The currently available cement products are Howmedica Simplex , Zimmer Osteobond and Codman Cranioplast. From the moment that the monomer liquid is added to the powder there are 4-8 minutes with an average of 5-6 minutes before the cement thickens and becomes unworkable. Cement is injected under lateral projection fluoroscopy imaging. The posterior aspect of the vertebral body is the key area to observe for posterior extension of cement. This is watched constantly during the injection. The injection is stopped as the cement starts to extend into some un wanted location such as the disc space or towards the posterior 1/4 of the vertebral body (where the risk of epidural venous filling and hence spinal cord compression is greatest). The injection is also discontinued if adequate vertebral filling is achieved. On average 4-6 ccs of cement can be injected sometimes it is possible to inject up to 8-9 ccs.

The second side is then anaesthetized, a 5-mm skin incision is made with a no.11 blade and a second needle is passed down the other pedicle and advanced into the vertebral body to the junction of the anterior and middle third of the vertebral body. Again cement is mixed with barium and injected. Conventionally this cement mixture is this same as the first batch. This is again injected under lateral projection fluoroscopy imaging. It is very difficult to visualize the cement against the pre existing cement density from the first injection. The posterior aspect of the vertebral body is the key area to observe for posterior extension of cement. This is watched constantly during the second injection.

After the cement is injected the needles are removed and steri strips are applied to the skin edges to apose them. Bethadine ointment is placed on each site. A dressing is placed over each level. The patient is then kept prone until the cement in the mixing bowl is set and is solidified. The patient is then moved on to a trolley and kept for observation for 3 hours prior to discharge.

Problems:

Control, Safety, visualization is the principle issues in this procedure today. It is essential to be able to visualize the cement as it is injected. This means that the cement must be visible under fluoroscopic X ray imaging. An opacifier has to be added to the cement in sufficient quantity that it allows the cement be clearly seen so the physician has no doubt where it is, how much he has injected and when he should stop the injection. Over injection can lead to filling of the veins around the spinal cord with cement and result in paraplegia or severe nerve compression. Pulmonary embolism has also recently been reported (14). The currently available cements are methyl methacrylate derivatives designed for use as cements that keep in place hip or knee prosthesis, or create skull bone flaps after Neurosurgery. Simplex and Osteobond have a 2% Barium added to them so they can be seen on X-ray. This is not adequate for safe vertebroplasty and the common practice is for radiologist to add more barium, or occasionally tungsten or tantalum to the mixture. Tantalum has recently become available and will be marketed in an FDA approved way by Cordis. Alternatives include calcium carbonate, Zirconium, or Oxalate or hydroxy appatite derivatives. Bio active bone cements that are intergratable , stimulate

bone growth or are resorbable, are in development by companies like Orthovita (who make Orthocomp, about to start clinical trials in Europe) , or Norion in the US. Howmedica/Stryker and Codman/Depuy have their own **"intelligent cement" (I want to trade mark that term)**

The key is visualization of the cement particularly on the second injection. A vertebral body has 2 pedicles, and these ones on the left one on the right are the routes of access to the vertebral body. About 40% of the time it is possible to adequately fill a vertebral body from a single injection. If this does not happen it is necessary to pass a second needle down the other pedicle and inject cement again. During the second injection it is very difficult and sometimes impossible to see the second cement injection as it is injected because of the pre existing identical density of the pre existing cement from the first injection. We cannot identify cement until it enters an area that the first injection didn't fill. As the cement fills the vertebral body it extends posteriorly towards the epidural venous plexus a group of veins that lie anterior to the spinal cord, It is always a challenge to identify the second cement injection before it fills areas likely to drain into these veins. Presently I use a 3 million US Dollar Biplane angiography suite to perform this procedure and its sophisticated software and hard ware help me to manage this difficult problem. There are 30-40 rooms like this in the US, perhaps 2 or 3 in Canada. As the procedure grows this most radiologists will not have equipment of this quality and so cements that are more easily visible are needed. The critical component of my idea and the area where it is novel and adds value is the first cement batch (Kit A) be of a lower yet sufficient density to inject than the second. The second batch of cement (Kit B) will be of such greater density that it will be possible to see it distinct from the first in the lateral projection.

The second critical area is that these cements be packaged in two separate sterile packs, so that if it is possible to achieve adequate vertebral filling with injection of the kit A cement, the second batch of cement will still be sterile so that it can be injected on another occasion in anther patient.

Kit A and Kit B will come packed in one large pack that will contain in the sterile drapes skin disenfectant necessary in the outer compartment.

Contents of Murphy vertebroplasty kit.

Create a situation where the hospital has to purchase a minimum stock.

Pack all this so it can be small enough keep in a refrigerator before use

Large outer pack sterile containing Drapes and disinfectant with 4 sponge tipped applicators

Inside the large pack, two separate sterile sealed packs that can be opened individually so that if only a unipedicular injection is needed to treat the patient the other set can be saved and used another day.

Packs labeled
Pack A and Pack B. The density of the barium in Pack A will be less than that in Pack B

Pack A Contents

LOCAL ANAESTHESIA
10 cc vial of 1% lidocaine without adrenaline.
10 cc syringe
16 gauge needle for aspiration of local anesthesia,
22-gauge long needle for local anesthesia injection.

No 11 blade on a disposable scalpel

11 gauge vertebroplasty needles. (for the standard "lumbar" kit.

Alternatively 13-gauge needle in a 13 gauge "Thoracic" kit.

Bone cement

One bag of cement containing 15 grams methyl methacrylate and barium. The critical issue is that these bags be labeled Bag A and Bag B. Bag A will have 5 grams of barium added. (Alternatively something like CaPo4 could be added.)

Regarding monomer I suggest vials of 12 cc's, which will allow the radiologist to decide how much he wants to add (some like more some use less monomer) so he /she can have the cement consistency that they like.

1 mixing bowl, one spatula
Syringes for monomer aspiration. Use a DMSO compatible syringe so the plunger doesn't swell in contact with the monomer. 8 X I cc syringes from MTI (contact Glenn Latham at 1 800 692 4892 ext. 224 or 1 949 466 1481 These are perfect

Pack B contents

LOCAL ANAESTHESIA
10 cc vial of 1% lidocaine without adrenaline.
10 cc syringe
16 gauge needle for aspiration of local anesthesia,
22-gauge long needle for local anesthesia injection.

No 11 blade on a disposable scalpel

11 gauge vertebroplasty needles. (For the standard "lumbar" kit.

Alternatively 13-gauge needle in a 13 gauge "Thoracic" kit.

Bone cement

One bag of cements containing 15 grams methyl methacrylate and barium. The critical issue is that these bags be labeled Bag A and Bag B. Bag B will have 10 grams of barium added. (Alternatively something like CaPo4 could be added.)

Monomer I vial of 12 ccs,

1 mixing bowl, one spatula
Syringes for monomer aspiration. Use a DMSO compatible syringe so the plunger doesn't swell in contact with the monomer. **8** X I cc syringes from MTI

Items such as needles mixing bowls, spatulas and syringes should be made available for individual sale.

Consider also the design of a hammer for use in introducing the needle. A flat design like a stick is good just add weight to the distal end/head. This must be reusable.

Key papers

1) Cotten A, Boutry N, Cortet B, Assaker R, Demondion X, Leblond D, Chastanet P, Duquesnoy B, Deramond H. Percutaneous vertebroplasty: state of the art. Radiographics 1998 Mar-Apr;18(2):311-20; discussion 320-3

Vertebroplasty is an effective new radiologic procedure consisting of the percutaneous injection of a biomaterial, usually methyl methacrylate, into a lesion of a vertebral body. This technique allows marked or complete pain relief and bone strengthening in most cases. The principal indications for vertebroplasty are osteolytic metastasis and myeloma, painful or aggressive hemangioma, and osteoporotic vertebral collapse with debilitating pain
that persists despite correct medical treatment. Radiography and computed tomography must be performed in the days preceding vertebroplasty to assess the extent of vertebral collapse, the location and extent of the lytic process, the visibility and degree of involvement of the pedicles, the presence of cortical destruction or fracture, and the presence of epidural or foraminal stenosis caused by tumor extension or bone fragment retropulsion. Leakage of methyl methacrylate during vertebroplasty may cause compression of adjacent structures and necessitate emergency decompressive surgery; thus, the procedure should be performed only in a surgical center. The decision to perform vertebroplasty should be made by a multidisciplinary team because the choice between vertebroplasty, surgery, radiation therapy, medical treatment, or a combination thereof depends on a number of factors. Radiologists need to be aware of the various indications for vertebroplasty and of potential future developments and applications of the procedure.

2) Jensen ME, Evans AJ, Mathis JM, Kallmes DF, Cloft HJ, Dion JE. Percutaneous polymethylmethacrylate vertebroplasty in the treatment of osteoporotic vertebral body compression fractures: technical aspects. AJNR Am J Neuroradiol 1997 Nov-Dec;18(10):1897-904

PURPOSE: To describe a technique for percutaneous vertebroplasty of osteoporotic vertebral body compression fractures and to report early results of its use. METHODS: The technique was used over a 3-year period in 29 patients with 47 painful vertebral fractures. The technique involves percutaneous puncture of the involved vertebra(e) via a transpedicular approach followed by injection of polymethylmethacrylate (PMMA) into the vertebral body. RESULTS: The procedure was technically successful in all patients, with an average injection amount of 7.1 mL PMMA per vertebral body. Two patients sustained single, nondisplaced rib fractures during the procedure; otherwise, no clinically significant complications were noted. Twenty-six patients (90%) reported significant pain relief immediately after treatment. CONCLUSION: Vertebroplasty is a valuable tool in the treatment of painful osteoporotic vertebral fractures, providing acute pain relief and early mobilization in appropriate patients.

3) Deramond H, Depriester C, Galibert P, Le Gars D. Percutaneous vertebroplasty with polymethylmethacrylate. Technique, indications, and results. Radiol Clin North Am 1998 May;36(3):533-46

Percutaneous vertebroplasty with acrylic cement consists of injecting polymethylmethacrylate into vertebral bodies destabilized by osseous lesions. The aim is to obtain an analgesic effect by reinforcing lesions of the spine. The major indications are vertebral angiomas, osteoporotic vertebral crush syndromes, and malignant spinal tumors. The clinically significant complications occur predominantly in patients with spinal metastatics, but in the great majority of cases they resolve with medical treatment. These complications occur in patients without posterior walls due to lytic disease and can result in cord compression. This problem has not occurred when the procedure is performed by a radiologist.

4) Cotten A, Dewatre F, Cortet B, Assaker R, Leblond D, Duquesnoy B, Chastanet P, Clarisse J. Percutaneous vertebroplasty for osteolytic metastases and myeloma: effects of the percentage of lesion filling and the leakage of methyl methacrylate at clinical follow-up. Radiology 1996 Aug; 200(2):525-30

PURPOSE: To determine whether the percentage of vertebral lesion filling and the leakage of methyl methacrylate have any clinical significance at follow-up. MATERIALS AND METHODS: Forty percutaneous vertebroplasties were performed for metastases (30 cases) and myeloma (10 cases) in 37 patients. A computed tomographic scan was obtained 1-8 hours after methyl methacrylate injection and was used to assess the percentage of lesion
filling by methyl methacrylate and the leakage of methyl methacrylate into the epidural tissues, neural foramina, intervertebral disks, venous plexus, and paravertebral tissue. The results were correlated with those obtained at clinical follow-up. RESULTS: Partial or complete pain relief was sustained in 36 of 37 patients. Pain relief was not proportional to

the percentage of lesion filling. Clinical improvement was maintained in most patients. The 15
epidural leaks, eight intradiskal leaks, and two venous leaks of methyl methacrylate had no clinical importance. Two of eight foraminal leaks produce nerve root compression that required decompressive surgery. One of 21 paravertebral leaks produced transitory femoral neuropathy. CONCLUSION: Pain relief can occur despite insufficient lesion filling. In most patients, intradiskal and paravertebral leaks of cement had no clinical importance.

5) Dufresne AC, Brunet E, Sola-Martinez MT, Rose M, Chiras J Percutaneous vertebroplasty of the cervico-thoracic junction using an anterior route. Technique and results. Report of nine cases. J Neuroradiol 1998 Jul; 25(2):123-8

Percutaneous vertebroplasty using fluoroscopy is a well known technique. Visualization of the posterior wall of the vertebra is mandatory. Good assessment of this part of the vertebra is usually difficult at the cervico-thoracic junction. We propose an original method to obtain adequate visualization of the posterior wall, avoiding superposition of the shoulders. Using this technique, we performed twelve vertebroplasties in nine patients (one angioma and eleven metastatic lesions). Clinical outcome was good for all patients, even a total filling of the vertebra body by the cement was obtained in only eight cases on twelve. No clinical complication was observed.

6) Bostrom MP, Lane JM. Future directions. Augmentation of osteoporotic vertebral bodies. Spine 1997 Dec 15;22(24 Suppl):39S-42S . Published erratum appears in Spine 1998 Sep 1;23(17):1922

Because current medical and surgical treatments of vertebral body fractures are less than adequate, there is a need for interventions that decrease the likelihood of occurrence of these fractures and improve the treatment options once they have occurred. One such broad category of intervention involves the fortification or augmentation of the vertebral bodies. In addition to prophylactically stabilizing osteoporotic vertebral bodies at risk for fracture,

augmentation of vertebral bodies that have already fractured may prove to be useful by reducing pain, improving function, and preventing further collapse and deformity. Vertebral body augmentation can also be used as an adjunct to fixation of internal hardware--for example, pedicle screws-in osteoporotic spines. A number of products are now available or are in clinical trials. The most promising products are injectable materials polymethylmethacrylate or mineral bone cement. The early clinical results using polymethylmethacrylate in percutaneous vertebroplasty for fractured vertebral bodies and the

results in vitro using an injectable mineral cement for vertebral body fortification are encouraging. Although the principle of vertebral body augmentation remains encouraging, data to support the widespread use of these techniques remain sparse, and the indications for their use should be more clearly defined.

7) Chiras J, Depriester C, Weill A, Sola-Martinez MT, Deramond H Percutaneous vertebral surgery. Technics and indications. J Neuroradiol 1997 Jun;24(1):45-59

Percutaneous vertebroplasty is a technique of interventional radiology, which allows to fulfill pathologic vertebral body with acrylic cement. This method is used to strengthen the vertebral body and reduce pain in some diseases involving the vertebra. Main indications are spine angiomas, metastases and osteoporosis. The vertebroplasty is realized under neuro leptanalgesia for cervical spine antero lateral way is used. For thoracic orlumbar vertebra, the way of approach is usually transpedicular; but in some cases, this approach is not possible: osteolysis of the pedicle, surgical osteosynthesis; in such cases, a postero lateral approach is realized. Technical incidents are not rare, but are usually asymptomatic. More frequent is venous filling with cement; the veins involved can be intra spinal (vertebral plexus) or paraspinal. Instead of this frequency pulmonary embolism in direct relation with the vertebroplasty where not reported. Extravasation in intervertebral disk or soft tissue can also be observed. This last incident can be in relation with the way of the needle or with a cortical rupture. Local complications are rare: rate of neurological deficit or infection is under 0.5%. Radicular pain is observed in 3.7% of cases. These complications are in close relation with the radiological involvement of the vertebra: cortical disruption, heterogeneous Lysis of the vertebral body. The frequency of complications is 1.3% in osteoporosis, 2.5% in spine angiomas and 10% in metastatic disease. Indications concern lesion involving the vertebral body: symptomatic spine angiomas; painful osteoporotic fractures after medical treatment or in patients with a high risk of decubitus complications; in metastatic disease, vertebroplasty is a way to consolidate the vertebral body and release pain. It can be useful in recurrent pain after chemotherapy and/or radiotherapy, and also in unstable vertebra to obtain stabilization before radiotherapy or chemotherapy treatment isolated or in combination with surgical osteosynthesis.

8) Tamayo-Orozco J, Arzac-Palumbo P, Peon-Vidales H, Mota-Bolfeta R, Fuentes F Vertebral fractures associated with osteoporosis: patient management. Am J Med 1997 Aug 18;103(2A):44S-48S; discussion 48S-50S

With the growing interest in new treatments aimed at preventing bone loss and conserving bone mass, insufficient attention has been given to symptomatic treatment of patients with vertebral fractures. Patients often believe that the pain and impaired mobility associated with these fractures are permanent and that little can be done to help. This is a serious misconception. Prompt intervention using a multidisciplinary approach can hasten

recovery from pain; improve mobility, flexibility, and speed of movement; and restore independence. Individualized care is needed because clinical features and degree of physical disability vary widely. Asymptomatic patients with vertebral fractures require evaluation and a management plan aimed at maintaining bone mass, improving functional status of the affected region, and preventing pain and new fractures. For patients with acute or chronic

pain, treatment of pain and functional limitations is the first priority, followed by functional rehabilitation and preservation of bone mass. A multidisciplinary approach to long-term care is recommended and includes lifestyle re-education, physical therapy, physical fitness training, neurologic and orthopedic evaluation, and, for some patients, use of an orthosis. After 4-6 weeks, those patients for whom pain is persistent require detailed study

to detect neurologic, myofascial, or orthopedic complications that can lead to chronic impairment of mobility. Vertebroplasty, surgery using different modalities, new exercise programs, and lifestyle modifications, together with more potent and effective

medications to improve bone quality, are options to be used in the individual patient. Well-designed studies are needed that specifically examine the management of these patients, particularly in the areas of pain relief and functional rehabilitation.

9) Cortet B, Cotten A, Boutry N, Dewatre F, Flipo RM, Duquesnoy B, Chastanet P, Delcambre B. Percutaneous vertebroplasty in patients with osteolytic metastases or multiple myeloma. Rev Rhum Engl Ed 1997 Mar;64(3):177-83

Osteolytic metastases and spinal myeloma lesions are difficult to treat because they denote disseminated malignant disease. The pain-relieving and other effects of radiation therapy are delayed. We evaluated short- and medium-term outcomes of vertebroplasty in this indication, inpatients with severe or excruciatingly severe pain (McGill-Melsack score 4 or 5) unresponsive to narcotics. PATIENTS AND METHODS: forty vertebras were treated in 37patients including 29 with bone metastases and eight with multiple myeloma. Mean age was 58 years (range 36-83). The spinal segment involved was the cervical spine in five cases, the thoracic spine in 12 and the lumbar spine in 23. Vertebroplasty was done under fluoroscopy guidance after premedication and local anesthesia. RESULTS: thirty-six patients (97.3%) reported a decrease in their pain 48 hours after the procedure; five of these patients (13.5%)were completely free of pain, 20 (55%) were significantly improved and 11 (30%) were moderately improved. One patient failed to respond. The clinical results were not correlated to the extent of vertebral body filling. Beneficial effects were increased or unchanged in 100% of cases after one month, 88.9% after three months and 75% after six months. Leakage of the cement outside the vertebral body occurred in 29 cases (72.5%), usually into theparaspinal soft tissues (n =

21,52.5%). Leakage was usually clinically silent and only two patients developed severe nerve root pain due to leakage into a neural foramen, with in both instances a favorable outcome after surgery. CONCLUSION: Vertebro- plasty is simple and effective for the treatment of osteolytic metastases and multiple myeloma lesions, but should be performed only in centers with neurosurgical and/or orthopedic surgery units because of the possibility of severe complications.

10) Ide C, Gangi A, Rimmelin A, Beaujeux R, Maitrot D, Buchheit F, Sellal F, Dietemann JL. Vertebral haemangiomas with spinal cord compression: the place of preoperative percutaneous vertebroplasty with methyl methacrylate. Neuroradiology 1996 Aug;38(6):585-9

We report on cervical and two thoracic vertebral haemangiomas with neurological disturbance successfully treated by percutaneous vertebroplasty followed by decompression surgery. Vertebroplasty consolidates the vertebral body and reduces the risk of haemorrhage. Subsequent surgery may be limited to decompressive laminectomy and resection of the epidural extension of the haemangioma. embolisation was also carried out in one case.Complete neuroimaging workup, including CT, myelo-CT and MRI, is necessary prior to treatment.

11) Weill A, Chiras J, Simon JM, Rose M, Sola-Martinez T, Enkaoua E Spinal metastases: indications for and results of percutaneous injection of acrylic surgical cement. Radiology 1996 Apr;199(1):241-7

PURPOSE: To determine the efficacy of percutaneous vertebroplasty in treating spinal metastases that result in pain or instability. MATERIALS AND METHODS: Thirty-seven patients (20 men, 17 women; aged 33-86 years) underwent 52 percutaneous injections of surgical cement into a vertebra (vertebroplasty) with fluoroscopic guidance in 40 procedures. Vertebroplasty was performed for analgesia in 29 procedures, stabilization of the vertebral column in five procedures, and both in six procedures. RESULTS: Twenty-four of the 33 procedures performed for analgesia that were evaluated resulted in clear improvement; seven, moderate improvement; and two, no improvement. Improvement was stable in 73% of patients at 6 months. In the procedure performed for stabilization, no displacement of treated vertebrae was observed (mean follow-up, 13 months). Three patients had transient radiculopathy due to cement extrusion, and two patients had transient difficulty in swallowing. CONCLUSION: Vertebroplasty of metastases is a minimally invasive procedure that provides immediate and long-term pain relief and contributes to spinal stabilization.

12) Gangi A, Kastler BA, Dietemann JL. Percutaneous vertebroplasty guided by a combination of CT and fluoroscopy. AJNR Am J Neuroradiol 1994 Jan;15(1):83-6

We describe the technique of percutaneous vertebroplasty using methyl methacrylate. We injected under the guidance of CT and fluoroscopy a group of 10 patients with back pain caused by a variety of vertebral lesions including severe osteoporosis (n = 4), hemangiomas (n = 5) and metastasis (n = 1). Over varying periods of follow-up (ranging from 4 to 17 months) none of the injected vertebral bodies demonstrated compression. All patients had relief of back pain; none had complications related to the technique. We

emphasize that the efficacy of this technique in preventing vertebral collapse could not be evaluated in this small sample; a well-controlled study would be required to determine the proper indications and efficacy of this treatment.

13) Kaemmerlen P, Thiesse P, Bouvard H, Biron P, Mornex F, Jonas P
Percutaneous vertebroplasty in the treatment of metastases. Technic and results. J Radiol 1989 Oct;70(10):557-62

The authors studied 20 patients with vertebral metastases. They injected in these metastases orthopaedic cement by a percutaneous technique under local anesthesis. The results are good for 16 patients, nul for 2 patients and we observed 2 complications. The authors conclude that the best indication is the painy somatic lysis of a vertebra without peri-radicular tumor.

14) Padovani B, Kasriel O, Brunner P, Peretti-Viton P
Pulmonary embolism caused by acrylic cement: a rare complication of percutaneous vertebroplasty. AJNR Am J Neuroradiol 1999 Mar;20(3):375-7

A pulmonary embolus of acrylic cement was present in a 41-year-old woman with Langerhans' cell vertebral histiocytosis (LCH) after percutaneous vertebroplasty. Chest radiograph and CT confirmed pulmonary infarction and the presence of cement in the pulmonary arteries. She was treated with anticoagulants, and responded favorably. This rare complication occurred because perivertebral venous migration was not recognized during vertebroplasty. Adequate preparation of cement and biplane fluoroscopy are recommended for vertebroplasty.

15) Kaemmerlen P, Thiesse P, Bouvard H, Biron P, Mornex F, Jonas P
Percutaneous vertebroplasty in the treatment of metastases. Technic and results. J Radiol 1989 Oct;70(10):557-62

The authors studied 20 patients with vertebral metastases. They injected in these metastases orthopaedic cement by a percutaneous technique under local anesthesis. The results are good for 16 patients, nul for 2 patients and we observed 2 complications. The authors conclude that the best indication is the painy somatic lysis of a vertebra without peri-radicular tumor.

16) Cotten A, Deramond H, Cortet B, Lejeune JP, Leclerc X, Chastanet P, Clarisse J
Preoperative percutaneous injection of methyl methacrylate and N-butyl cyanoacrylate in vertebral hemangiomas. AJNR Am J Neuroradiol 1996 Jan;17(1):137-42

PURPOSE: To investigate the usefulness of preoperative percutaneous injections in vertebral hemangiomas. METHODS: Four patients presented with complicated vertebral hemangioma (spinal cord compression in three cases, intermittent spinal claudiction in one case). A three-part treatment was performed: initially, arterial embolization in three cases; 1 day later, percutaneous injections of methyl methacrylate into the vertebral body to
strengthen it and of N-butyl cyanoacrylate into the posterior arch to optimize hemostasis during surgery; finally, the day after percutaneous injections, decompressive laminectomy and epidural hemangioma excision (when present). RESULTS:

Laminectomy was performed with minimal blood loss. The epidural component present in three cases was excised without any difficulty. The follow-up (average, 20 months) showed no evidence of vertebral collapse. CONCLUSION: Percutaneous injections of methyl methacrylate and N-butyl cyanoacrylate might be useful before surgery for vertebral
hemangiomas.

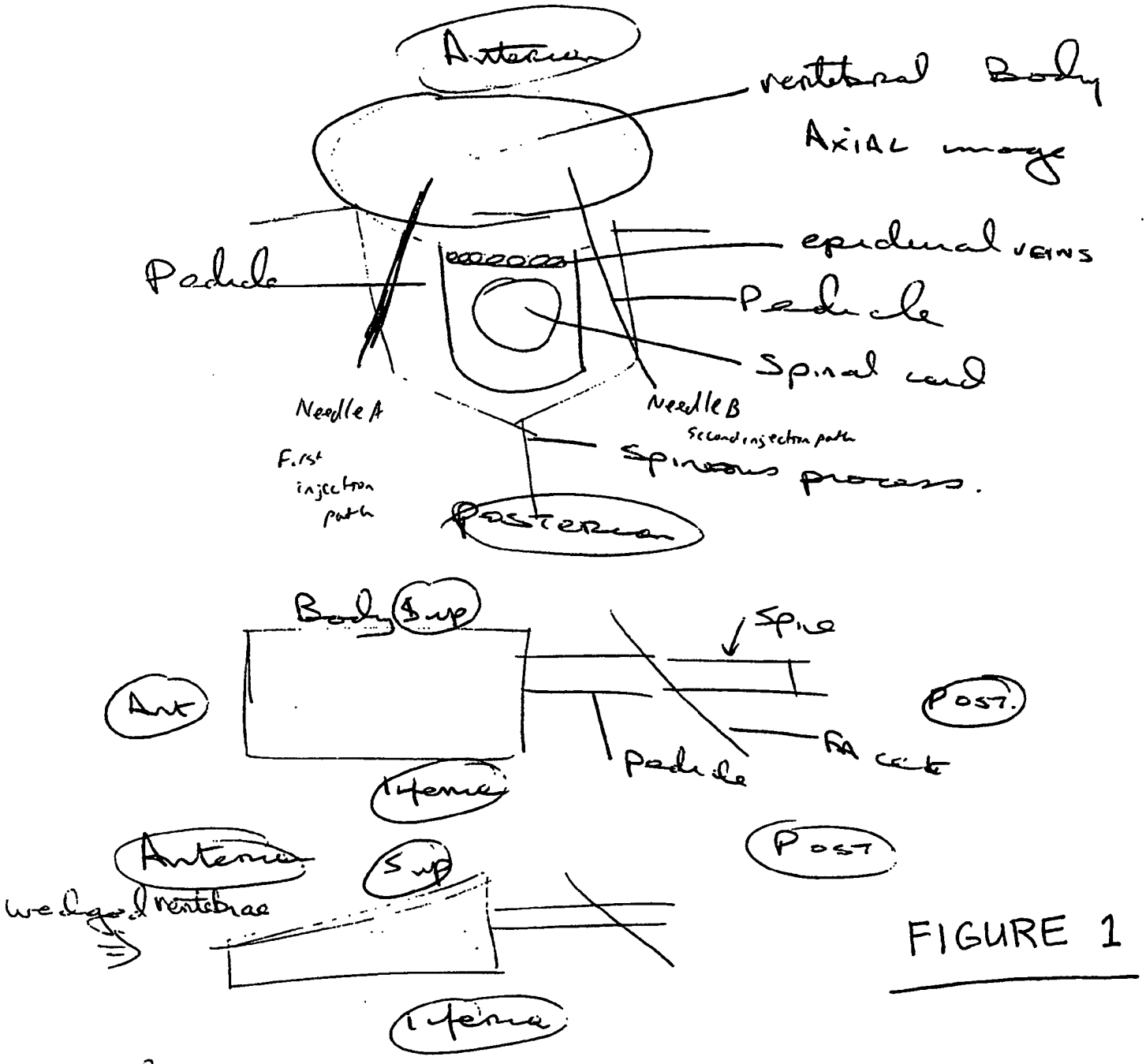

FIGURE 1

Wedged = Fractured + Collapsed